Request Entry of the Amendment

Applicants submit that the foregoing amendment should be entered as a clarification of the claim language that does not give rise to a substantial new question of patentability. As noted by the Office Action, Applicants have previously argued that the present claims are distinct over the cited prior patent because they recite the additional step of adjusting the mass spectrometer desolvation conditions such that the signal strength of said standard compound bound to said target molecule is from 1 % to about 30 % of signal strength of unbound target molecule (the "adjusting" step). By the foregoing amendment, Applicants have merely clarified what was intended by "operating performance conditions of said mass spectrometer." Thus, the issue presented by the foregoing amendment has already been presented to the Patent Office, and has presumably been considered on its merits. Moreover, as discussed in more detail below, Applicants submit that the claims are in condition for allowance. Hence, entry of the amendment is proper and is respectfully solicited.

Non-statutory obviousness-type double patenting

Claims 30-32 and 34-46 have been rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 10-19 of U.S. Patent No. 6,329,146 B1 (Crooke et al.: "the '146 patent"). Applicants respectfully request reconsideration The Office Action states that "...the features upon which applicant relies (i.e., applicant argues that "[t]he claimed process includes the step of adjusting the mass spectrometer desolvation conditions using standard ligand to provide resolution of a low-strength labile signal" (see specification, page 11, lines 29-33) are not recited in the rejected claims." In the interest of clarifying and focusing the issues, Applicants have amended claims 30 and 46 to replace the pharase "operating performance conditions of said mass spectrometer" with "mass spectrometer desolvation conditions" Applicants submit, as previously stated in the July 11, 2003 response, that the '146 patent neither teaches nor suggests adjusting the mass spectrometer performance conditions, i.e. desolvation conditions, as claimed.

Applicants note that they have previously argued patentability of the present claims over the '146 patent claims, based upon the step of adjusting the mass

spectrometer desolvation conditions. The Office Action objected to this line of argument, stating that the language on which Applicants relied was not recited in the claims. While Applicants submit that, when properly read in view of the specification, the claims as previously presented clearly recited a step that was neither taught nor suggested by the prior art, Applicants have amended the claims to clarify the issues and thereby expedite prosecution.

Applicants note that the Office Action did not state or imply that adjusting the mass spectrometer desolvation conditions would have been obvious to the person having ordinary skill in the art at the time of the present invention. Indeed, the record is entirely bereft of any evidence that the person having ordinary skill in the art would have found it obvious to adjust the mass spectrometer performance (desolvation) conditions such that the signal strength of a standard compound bound to the target molecule is from about 1 % to about 30 % of signal strength of the unbound target molecule. Absent such evidence, the '146 patent fails to provide sufficient teaching or suggestion of the present invention to support an obviousness-type double patenting rejection. Applicants therefore request that the rejection for obviousness-type double patenting be withdrawn.

35 U.S.C. § 102

Claims 30-32 and 34-46 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the '146 patent. The Office Action states that "the limitation of adjusting the operating performance conditions of the mass spectrometer such that the signal strength of the standard compound bound to the target molecule is from 1% to about 30% of signal strength of unbound target molecule is inherently a routine optimization step in the method of mass spectrometry."

Anticipation under 35 U.S.C. § 102(e) requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc v. Union Oil Co.,* 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed.Cir. 1987).

Applicants respectfully request reconsideration in light of the present claim amendments wherein the element of "adjusting the mass spectrometer desolvation conditions" has replaced "operating performance conditions of said mass spectrometer".

Adjustment of mass spectrometer desolvation conditions is not disclosed in the '146 patent, nor is it expressly or inherently described. There is absolutely no evidence of record that such adjustment step would have been inherently performed by one practicing the '146 patent. As the requirements for an anticipation rejection have not been met, Applicants respectfully request that the 35 U.S.C. § 102(e) rejection be withdrawn.

Conclusion

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes an interview would expedite prosecution of this application, please telephone the undersigned at (760) 603-2473.